

**Notice of Allowability**

Application No.	Applicant(s)	
10/010,283	BAUER ET AL.	
Examiner	Art Unit	
Jennifer Kim	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1.  This communication is responsive to 7/27/2007.
2.  The allowed claim(s) is/are 9,11-17 and 21-58 (renumbered as 1,2-8 and 9-46 respectively).
3.  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All    b)  Some\*    c)  None    of the:
  1.  Certified copies of the priority documents have been received.
  2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3.  Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4.  A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5.  CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a)  including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached  
1)  hereto or 2)  to Paper No./Mail Date \_\_\_\_\_.
  - (b)  including changes required by the attached Examiner's Amendment / Comment or in the Office action of  
Paper No./Mail Date \_\_\_\_\_.Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6.  DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1.  Notice of References Cited (PTO-892)
2.  Notice of Draftsperson's Patent Drawing Review (PTO-948)
3.  Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4.  Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5.  Notice of Informal Patent Application
6.  Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_.
7.  Examiner's Amendment/Comment
8.  Examiner's Statement of Reasons for Allowance
9.  Other \_\_\_\_\_.



Jennifer Kim  
Primary Examiner  
Art Unit 1617

## REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance:

The claims are allowable over the cited prior art because the prior art does not teach, disclose nor make obvious the claimed method for reducing the frequency and/or intensity of chronic obstructive pulmonary disease (COPD) exacerbations experienced by a patient suffering from COPD, which method comprises administering to the patient via inhalation (i) a first active ingredient which is formoterol, a pharmaceutically acceptable salt or solvate thereof, or a solvate of such a salt; and (ii) a second active ingredient which is budesonide, wherein the method is effective to reduce the frequency and/or intensity of exacerbations in the patient, the first and second active ingredients are administered simultaneously, and the molar ratio of (a) formoterol in the first active ingredient to (b) the second active ingredient is from 1:555 to 2:1.

The cited prior art of record, Carling et al. teach a medicament containing effective amounts of formoterol and budesonide in combination for simultaneous, sequential or separate administration by inhalation in treatment of respiratory disorder. However, Carling et al. do not teach the treatment of specific disorder of COPD.

The cited prior art of record, Renkema et al. teach the effects of long-term treatment of COPD with corticosteroids (i.e. budesonide). However, the dosage employed by Renkema et al. is high dose of 1600ug budesonide and suggests that still higher doses of corticosteroids are needed in patients with COPD. Further, the

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reference warrants further studies to clarify the effect in larger numbers of the patients with COPD. Therefore, there is no motivation to employ the combination with specific amounts ratio for the treatment of COPD because there is no reasonable expectation of successfully treating COPD without specific teaching and suggestion from the prior art.

Applicants presented declaration showing the synergistic effect of the claimed combination therapy in the treatment of COPD. (the 2005 Trofast Declaration) and it is persuasive.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Jennifer Kim  
Primary Examiner  
Art Unit 1617

Jmk  
October 1, 2007